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IN THE

Supreme Court of the United States

MEDIMMUNE, INC.,

Petitioner,

v.

GENENTECH, INC., ET AL.

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF THE BOSTON PATENT LAW ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF GENENTECH, INC., ON THE MERITS

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INTEREST OF *AMICUS CURIAE*

The Boston Patent Law Association ("BPLA") is a non-profit association of intellectual property professionals that provides programs and forums for the exchange of ideas and information about patent and other intellectual property rights. The BPLA favors a healthy and balanced patent system, which in turn fosters innovation and bolsters the American economy. Departing from the case or controversy requirement of Article III, however, may ultimately upset the balance in the patent system and, correspondingly, discourage innovation and technology licensing. As such, this case evokes the BPLA's interest.[1]

SUMMARY OF ARGUMENT

The Court of Appeals for the Federal Circuit correctly determined that MedImmune's mere desire to challenge the Cabilly II patent while still retaining the benefits of its license with Genentech did not create an actual controversy sufficient to trigger Article III jurisdiction. The BPLA agrees with the Federal Circuit's reasoning in this and other cases holding that a licensee in good standing may not challenge the licensed patents in court. *See, e.g., Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004); *MedImmune, Inc. v. Centocor, Inc.*, 409 F.3d 1376 (Fed. Cir. 2005).

Rather than repeat or bolster the Federal Circuit's legal analysis in these cases, the BPLA instead wishes to dispel the impression, advanced by MedImmune, that the patent system is somehow off-kilter, that patents are unsound, and

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[1] Pursuant to Supreme Court Rule 37.6, no party or its counsel authored any part of this brief. No person or entity, other than the BPLA and its counsel, Bromberg & Sunstein LLP, contributed money for the preparation or submission of this brief. The parties have consented to the filing of this *amicus* brief. The consent letters have been lodged with the Court.

that the mere hint of an invalid patent justifies a departure from the Article III actual controversy requirements.

In short, contrary to MedImmune's contentions, there is no plague of bad patents threatening licensing, competition, or innovation. As such, there is no need to make an exception to the Article III controversy standard as a way to address a perceived but unsubstantiated problem with the quality of patents. On the other hand, writing a new rule that allows licensees in good standing to challenge licensed patents will upset the balance between licensors and licensees, create uncertainty, and thus cause intellectual property owners to lose faith in licenses as a valid means of (a) profiting from innovation and (b) settling infringement disputes efficiently.

Thus, the BPLA's argument is two-fold. First, the patent system is not broken. Statistics reveal that issued patents are generally sound and deserve their statutory presumption of validity. Accordingly, there is no policy reason to allow licensees in good standing to challenge patents. And even if the statistics were otherwise, even if there were a plague of bad patents infesting the economy, the response should come from Congress or the Executive branch, not from this Court. For example, Congress and the United States Patent and Trademark Office ("PTO") could takes steps to improve patent examination so that fewer defective patents issue.

Second, if anything, public policy justifies the Federal Circuit's holding. A policy favoring settlement of litigation through licensing trumps a policy of removing allegedly invalid patents from the economy. Technology licensing generates billions of dollars and is increasingly important to the American economy. Licensing also benefits consumers by ensuring that innovative products, life-saving drugs and medical devices, and other inventions make their way to the market. A ruling that allows an intellectual property user to take a license only to turn around and challenge the

underlying patent when it becomes expedient to do so, however, will ultimately devalue licenses, making them less certain and less efficient as a means for balancing the needs of intellectual property owners and users.

ARGUMENT

I. PATENTS ARE SOUND; THUS, THERE IS NO POLICY REASON FOR UNDERMINING THE ARTICLE III CONTROVERSY STANDARD

There is nothing to suggest that a plague of invalid patents threatens the U.S. economy and that, as MedImmune contends, there is a crisis somehow justifying a ruling that, for the first time, would allow licensees in good standing to challenge allegedly invalid patents. Just the opposite holds true. Statistics suggest that the PTO is doing its job and is, on the whole, issuing valid patents. Thus, there is no urgent reason to disturb the Federal Circuit's refusal to depart from the actual controversy requirement. But even if there were a problem with patent quality, the fix should come from Congress, not from this Court.

A. Patents Are Generally Sound

According to John Dudas, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, the notion that the patent system is broken is based on misperception, not on fact. *See* Neil E. Graham, *Perception Gap Hindering Efforts to Improve Patent System, Dudas Says*, 71 Pat. Trademark, & Copyright J. 374 (2006). In fact, patent quality is improving. For example, Dudas corrects a misperception that the increasing number of patent applications has led to decreasing patent quality. Statistics show that the percentage of applications granted has actually decreased (suggesting that the PTO is being more selective) while the number of patent examiners

has increased to keep up with demand. *Id.* Moreover, despite a perception that up to 40% of all patents are overturned in court, "less than 1/20th of one percent of all patents that issue are actually overturned in court." *Id.*

Congress has determined that U.S. patents are presumed valid. 35 U.S.C. § 282. That presumption of validity stems, in part, from the presumption that a government agency, such as the PTO, does its job well. *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984). That presumption is well deserved.

A review of the patent application process shows that PTO examiners are far from bored clerks rubber-stamping applications until the clock strikes five. Contrary to MedImmune's contention, the PTO does not grant every application it receives. Rather, the PTO does its job conscientiously and scrutinizes each application for compliance with all statutory requirements for patentability.

Specifically, when an inventor files an application for patent, the PTO assigns the application to an examiner versed in the technology of the claimed invention. After reviewing the application and searching for relevant prior art, the examiner typically rejects the application for one or more alleged defects and states his or her reasons in a so-called "office action." A patent application often receives not just one but two rounds of office actions. To overcome a rejection, the applicant must justify the patentability of the invention (*e.g.*, by distinguishing prior art cited by the examiner). In some instances, the applicant must narrow the scope of the claims to overcome the rejection.

The PTO issues office actions rejecting patent claims roughly 90% of the time. Indeed, a patent almost never issues on the first pass. *See, e.g.*, Andrew T. Zidel, *Patent Claim Construction in the Trial Courts: A Study Showing the*

Need for Clear Guidance from the Federal Circuit, 33 Seton Hall L. Rev. 711, 717–18, n.49 (2003) (giving an overview of patent prosecution and positing that claims are initially rejected 75–100% of the time); Procedure for Obtaining U.S. Patent, *at* http://www.angenehm.com/pat_faqs4.html (last visited July 23, 2006) ("The USPTO examines the application and in about 90% of the cases finds reason why the patent should not issue"); Larry J. Guffey, *Business Method Patents: What They Are — Why Clients and Service Providers Should Care*, 33 Md. B.J., July/Aug. 2000, at 25, 28 (2000) (initial rejection of patent claims occurs about 80% of the time and there are usually two rounds of office actions per application); Ronald E. Smith, The Ten Commandments of Inventing, *at* www.library.okstate.edu/patents/tencmds.htm (last updated June 26, 2006) ("According to PTO statistics, about 90 percent of all patent applications are initially rejected").

Not every application results in a patent. Rather, contrary to MedImmune's claim that 74% to 98% of all patent applications are granted, currently only about 50% of applications mature into patents. As seen in Figure 1 below, the percentage of patents granted has declined over the years. Moreover, as seen in Figure 2 below, the number of patents granted has leveled off at 180,000 per year, even as the number of applications has risen.[2]

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[2] The BPLA based Figures 1 and 2 on statistics compiled by the PTO. *See* U.S. Pat. & Trademark Office, *U.S. Patent Statistics Chart: Calendar Years 1963–2004*, *available at* http://www.uspto.gov/go/taf/us_stat.htm (last visited July 23, 2006) [hereafter *USPTO Patent Statistics*].

Figure 1. Percentage of Patents Granted Per Year

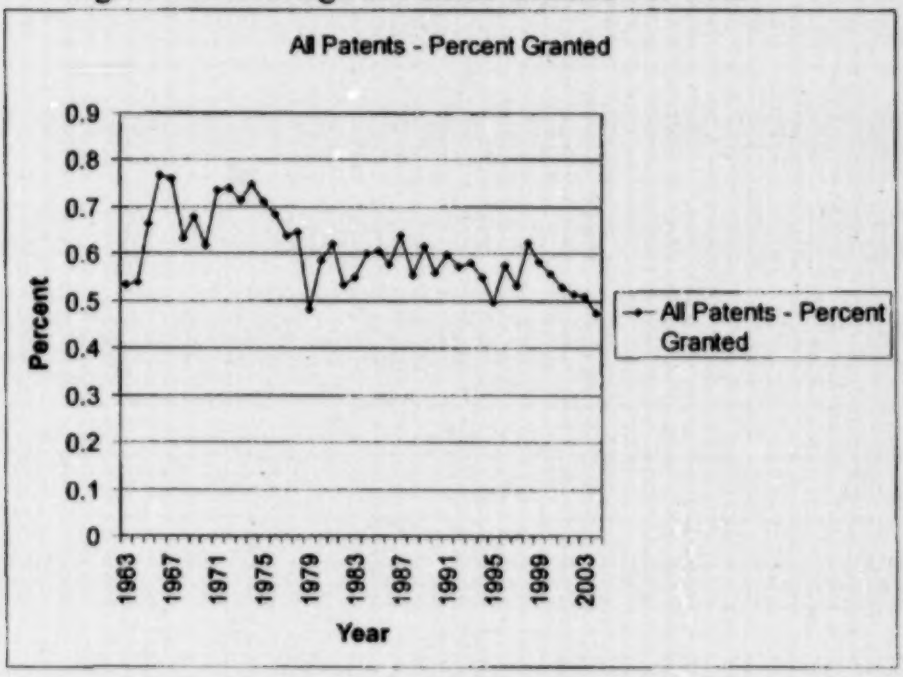
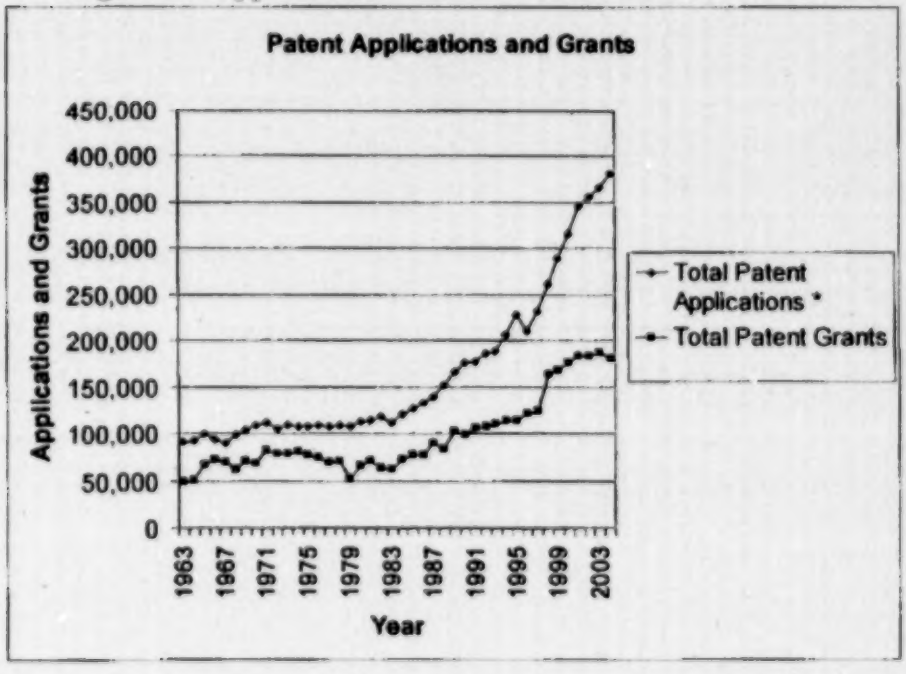


Figure 2. Applications and Grants Per Year



These trends suggests that the PTO is exercising appropriate selectivity. Indeed, the PTO appears to be getting stingier in granting patents. Perhaps, given the emergence of better

prior art searching capabilities (specifically, the use of computer and Internet prior art databases), the PTO is becoming even better at its job of rigorously examining patent applications.[3]

In some industries, the percentage of patent grants is significantly below the 50% level. For example, business method patents, frequently a target of criticism (most recently in the *eBay v. MercExchange* case), have been maligned as too easy to obtain. In March 2000, the PTO moved to address such criticism and thus hired and trained additional examiners and instituted a second level of patent review. *See* John R. Allison & Emerson H. Tiller, *The Business Method Patent Myth*, 18 Berkeley Tech. L.J. 987, 995 (2003). As a result of these and other improvements at the PTO, the percentage of business method patents granted fell from 56% to 36% in one year alone. *Business Method Patents: Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary*, 107th Cong. 58 (2001) (statement of Ronald E. Myrick, President, Intellectual Property Owners Association). Under Secretary Dudas notes that the current allowance rate for business method patents is only about 11%. Graham, 71 Pat., Trademark & Copyright J. at 374.

The PTO has also put in place a second level of review. After the patent examiner allows an application, PTO supervisors test the allowed claims for patentability and thus exercise quality control. The patent allowance error rate

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[3] Figures 1 and 2 track the results of all patent applications from 1963 to 2004, including utility, design, and plant patents. But when utility patents only are examined (*i.e.*, the type of patent involved in this case), the numbers are even more telling. For example, in 2004, U.S.-based inventors filed 189,536 applications for utility patents. In that same year, only 84,271 patents were granted to U.S.-based applicants. That grant rate was only 44%. *See USPTO Patent Statistics*.

(*i.e.*, the percentage of allowed patents rejected after this second level of review) in 2005 was only about 4%, down from 5.32% in 2004. U.S. Pat. & Trademark Office, Proposed Rule Changes to Focus the Patent Process Involving Continuations, Double Patenting and Claims (Mar. 29, 2006), *at* http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/connipla032906v1_text.html.

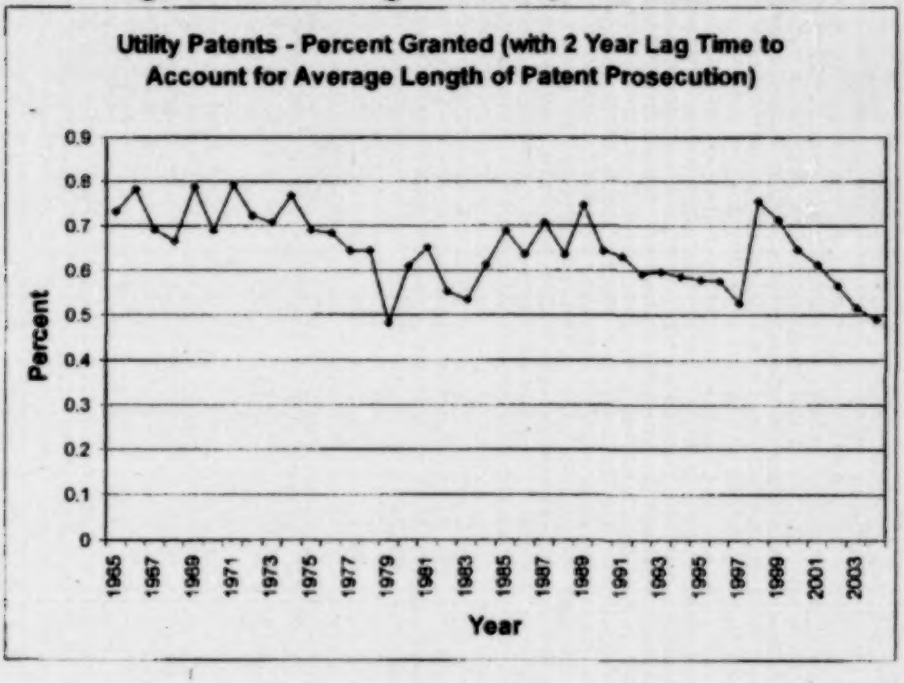
But that is not the end of PTO review. Patents can also be subjected to reexamination, either at the request of the patentee or, more often, an opponent. Indeed, in this case, MedImmune has requested reexamination of the Cabilly II patent (and thus does not even need to challenge the patent in court). In a reexamination, the requestor submits to the PTO prior art references and arguments against patentability that the PTO had not considered the first time. No presumption of validity applies. Even so, reexamination results in cancellation of the patent in only about 9.2% of the cases. That statistic alone confirms that the PTO generally did its job well the first time. In about 23% of the cases, the patent claims remain unscathed. In the rest of the cases, some claims are amended or some are cancelled but the patent as a whole survives. *See* Stuart J. Graham *et al.*, Post-Issue Patent "Quality Control": A Comparative Study of US Patent Re-examinations and European Patent Oppositions, 34 (2002), *available at* http://repositories.cdlib.org/iber/econ/E02-321 (analyzing all U.S. patents reexamined from 1980 to 1999).

As noted above, MedImmune claims that 74% to 98% of all applications are granted. *Brief for Petitioner* at 47. MedImmune derives these figures from a 2003 report by the Federal Trade Commission ("The FTC Report"). Fed. Trade Comm'n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003). MedImmune fails to mention, however, that the FTC Report itself notes that there is a dispute over these figures and that,

for example, recent research has cast doubt on the 98% figure. *See id.* at ch. 5, 6 & nn.41–42; *see also* Robert A. Clarke, *U.S. Continuity Law and its Impact on the Comparative Patenting Rates of the US, Japan and the European Patent Office*, 85 J. Pat. & Trademark Off. Soc'y 335, 337–38 (2003) (noting that the 98% figure results from double counting errors).

The FTC Report proves only that the numbers can be deceiving. Thus, to test the BPLA's own calculations, the BPLA recalculated a subset of patents (utility patents, which is the category of patent involved in this case) and applied a two-year lag to account for the average length of patent prosecution. That is, an application filed in, say, 2002, will, on average, not be granted until 2004 or later. As seen in Figure 3 below, however, the trend is the same: the patent grant rate has steadily declined since the late 1990s, dipping to roughly 50% in recent years.

Figure 3. Percentage of Utility Patents Granted



As seen above, the PTO is continuing its trend of applying more scrutiny to utility patents. The result is that the allowance rate has been declining since before the Cabilly II patent issued.

MedImmune makes a similarly misleading argument about the success of patent validity challenges, claiming that 45% of patents are held invalid when validity is challenged and litigated to final judgment. *Brief for Petitioner* at 47 (*citing* FTC Report, ch. 5 at 6). But this figure, if accurate, proves nothing. Even the FTC Report itself warns that the figure should be "interpreted with caution . . . [because] self-selection in bringing and settling suits makes it unlikely that patents litigated to final results are fully representative of patents as a whole." *FTC Report*, ch. 5 at 6 n.38 (citing *Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy: Hearing Before the Federal Trade Commission* at 92–93 (Jul. 10, 2002) (statement of Glynn S. Lunney, Jr.)); *see also* James Bessen & Michael J. Muerer, *Lessons for Patent Policy from Empirical Research on Patent Litigation*, 9 Lewis & Clark L. Rev. 1, 3–4 (2005) (patent suits "constitute a small and uncharacteristic subset" and that "selection bias distorts inferences based on statistics like patent holder win rates at trial"). In other words, disputes involving strong arguments for or against infringement and validity tend to resolve before trial, leaving only close cases for trial and appeal. One would expect a roughly 50% validity rate when such close cases go to final judgment. Thus, the 45% figure is unsurprising and meaningless.

B. Any Solution, if One Is Needed, Should Come from Congress and the PTO

Granted, some patents escape effective scrutiny in the PTO and are defective. The BPLA does not claim that the system is perfect. But MedImmune's proposed solution — to allow

all licensees in good standing to challenge the licensed patents, whether those patents are valid or not — is too extreme and, ultimately, will discourage licensing. If there is a problem with patent quality, the solution should not be to upset the entire intellectual property system. Instead, Congress and the PTO should address the problem at its alleged source, whether by allocating appropriate funds to the PTO or otherwise by amending PTO rules to promote more effective patent scrutiny.

Prominent inventors like Dean Kamen prefer fixing any perceived problem at its source by improving the PTO's ability to examine patents. In recent testimony to the House Subcommittee on Courts, the Internet, and Intellectual Property, Mr. Kamen called for more funding to improve PTO examination of patents. In Mr. Kamen's opinion, "[w]ith state of the art search tools and access to the world's technical literature at their fingertips, along with proper training, supervision, and adequate time to do a quality job, many of the real and perceived problems with the patent system should fade away." *Patent Trolls: Fact or Fiction: Hearing Before the Subcomm. On Courts, the Internet, and Intellectual Property of the H. Comm on the Judiciary*, 109th Cong. 83 (2006) (statement of Dean Kamen, President, DEKA Research & Development Corp.) [hereafter *Kamen Congressional Testimony*].[4]

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[4] Mr. Kamen, a member of the National Inventors Hall of Fame and recipient of the Heinz Award in Technology, among other honors, holds more than 150 U.S. and foreign patents, including patents directed to life-saving technologies like infusion pumps for neonates, wearable insulin pumps for diabetics, kidney dialysis machines for home use, and heart stents. Mr. Kamen's company, DEKA Research & Development Corporation, licenses many of these patents to medical device companies, who manufacture and market these life-saving products. *Kamen Congressional Testimony, supra*, at 1.

Under Secretary Dudas reports that many PTO initiatives to improve and streamline patent examination have already borne fruit and have improved patent quality, for example, by lowering the allowance error rate. Indeed, as seen above, when the PTO hired and trained additional examiners and implemented changes in the way it reviews applications for business method patents, quality improved dramatically. More initiatives, such as the hiring of additional examiners, are underway. Graham, *Perception Gap*, *supra*, at 374. Thus, experience shows that increased funding and legislation will actually pay dividends.

As argued in Section II below, rewriting jurisdiction rules to allow licensees in good standing to sue will upset the balance between licensors and licensees, between intellectual property creators and users. In particular, allowing licensees in good standing to sue will undermine the confidence that innovators and investors have in licensed patents. Any rule that undermines faith in intellectual property will be, in the words of Mr. Kamen, like "flood[ing] the building to put out a fire in a wastepaper basket." *Kamen Congressional Testimony*, *supra*, at 83.

II. ALLOWING LICENSEES IN GOOD STANDING TO SUE WILL UNDERMINE LICENSES AND HARM THE ECONOMY

MedImmune was pleased to take a license from Genentech when it sold no products covered by a licensed patent and thus paid no royalties. The license cost MedImmune almost nothing. MedImmune benefited from that *de facto* royalty-free license for a number of years, during which time MedImmune enjoyed peace (for free) from litigation. As MedImmune concedes, when it agreed to the license, it "was a new company unable to afford extended litigation and unwilling to risk crippling infringement judgments . . . ." *Petition for a Writ of Certiorari* ("Petition") at 3.

After taking the license, MedImmune began to market a commercially successful product, Synagis®, which, according to MedImmune, accounts for 80% of its profits. *See* Petition at 4. Back in 1997, however, when MedImmune negotiated the license, MedImmune obtained a low royalty rate because, at the time, it had not yet gained FDA approval to sell Synagis® and thus lacked any track record of commercial success (which is often a factor in determining a royalty rate). *See Brief of Respondent Genentech, Inc.*, at 5–8 ("The resulting license terms reflected these advantagesous bargaining conditions. The upfront payment was modest, and the royalty rate was heavily discounted").

But after Synagis® became profitable and as soon as MedImmune learned it would have to pay royalties—which would cut into MedImmune's substantial profits from the drug—MedImmune sought to challenge the Cabilly II patent while preserving its low royalty rate. Indeed, MedImmune apparently admits that the increasing profitability of the product was the impetus for this lawsuit: "With demand for Synagis® growing, and payments to Genentech correspondingly rising, on April 11, 2003, MedImmune brought suit . . ." *Brief for Petitioner* at 7.

MedImmune, it seems, has a history of ducking inconvenient infringement litigation (*e.g.*, before Synagis® became profitable and the stakes were low) by taking a license and then challenging the underlying patent when it becomes expedient to do so (*e.g.*, after Synagis® became profitable and the stakes became high). *See MedImmune, Inc. v. Centocor, Inc.*, 409 F.3d 1376, 1377-78 (Fed. Cir. 2005) (describing behavior similar to MedImmune's in this case and affirming dismissal for lack of an actual controversy).

MedImmune cannot complain that it was somehow tricked. When MedImmune signed up for the license, it knew that the

license covered a number of pending patent applications, including the application that eventually matured into the so-called "Cabilly II patent." *Petition for Writ of Certiorari* at 3. ("The license package also included . . . several patent applications that were pending, among them what became the Cabilly II patent . . .").

This calculating behavior does not justify departing from the Article III actual controversy standard. Allowing MedImmune to maintain its declaratory judgment action will have the unintended and harmful result of undermining faith in intellectual property licenses. But public policy encourages licensing and settlement of patent disputes, even if some allegedly invalid patents are left unchallenged.

A. The U.S. Benefits From Licenses

The United States benefits enormously from the licensing of patented technologies. Thus, a judicial or legislative body should exercise extreme caution before tampering with the current and long-existing balance between and expectations of licensors and licensees.

Institutions responding to an Association of University Technology Managers survey in 2004 reported that 137 entities had introduced 567 new commercial products to the marketplace under license agreements with commercial partners. *See* Assoc. of University Tech. Managers, *AUTM U.S. Licensing Survey: FY 2004: A Survey Summary of Technology Licensing (and Related) Performance for U.S. Academic and Nonprofit Institutions, and Technology Investment Firms* 2 (Ashley J. Stevens et al. eds., 2005) *available at* http://www.autm.net/events/File/FY04%20Licensing%20Survey/04AUTM-USLicSrvy-public.pdf.

In the same year, licensing income totaled $1.385 billion spread out among 196 institutions. *Id.* at 3. Some of the

new products resulting from U.S. licensing activities included improved blood glucose monitoring devices for diabetics, an experimental vaccine to combat parasitic infections, and a chemical decontaminant capable of destroying chemical warfare agents. *Id.* at 3–9. Educational and non-profit institutions benefit from licensing by gaining revenue sources to help pay for further research. Indeed, in 2000 alone, universities realized over $1 billion from licensing and capitalizing intellectual property. Bessen & Muerer, *supra*, at 13.

Well-known institutions like Harvard University, the Dana-Farber Cancer Institute, and St. Jude Children's Research Hospital frequently obtain patents and license their discoveries to others. *See* Assoc. of University Tech. Managers, *supra*, at 31–32

Manufacturers also benefit from being able to make and sell new products that the inventors had no interest in making or could not have made themselves. Indeed, even traditional and Rust Belt manufacturers like John Deere recognize that "the ability to keep inventing new products that are useful to customers is still the key to Deere's growth." Carol Hymowitz, *For Now, the Focus Is More on Innovation than on Budget Cuts*, Wall St. J., July 17, 2006, at B1. Deere, however, recognizes that it would be too costly to do all of its research and development in-house, which would mean hiring more engineers and competing for talent with high-tech companies, thus driving up costs. Instead, "[t]o stretch research dollars, Deere works with universities and small companies" to augment its development of innovative products. *Id.*

In other words, universities and small businesses can profit from licensing their discoveries to large manufacturers, who in turn profit by reducing the costs of innovation. That's the idea behind Mr. Kamen's success. As Mr. Kamen told the

House Subcommittee, his business model is to invent, not to manufacture, market, and sell. Thus, he licenses his patented technologies to companies that are better able to bring Kamen's life-saving technologies to market. In turn, the companies get exclusive patent protection without having to spend as much as they otherwise would on research and development. *Kamen Congressional Testimony*, *supra*, at 20–22.

Large companies also license their own discoveries to others, not only to make money but also to commercialize their discoveries more widely. For example, IBM earned $367 million in 2005 alone from licensing. IBM, *2005 Annual Report* 26 (2006), *available at* ftp.software.ibm.com/annualreport/2005/2005_ibm_annual.pdf. Hewlett-Packard gains roughly $200 million "worth of value from its intellectual property" annually, which includes royalty payments to the company and discounts on royalty payments to other companies that it would otherwise have to pay. Michael Kanellos, *HP Plays the Patent Game*, CNET News.com, Nov. 10, 2005, *at* http://news.com.com/HP+plays+the+patent+game/2100-1008_3-5944056.html.

In the biotech and pharmaceutical industries (those implicated in this case), the licensing of patents has led to enormous benefits for the health of the American people. For instance, Taxol, a potent cancer-fighting drug, was the result of Florida State University Professor Robert Holton's 1991 invention of a way to synthesize paclitaxel, the active compound in Taxol, using the compounds found in the needles and twigs of the common English Yew tree. Holton's invention allowed Taxol to be mass produced more economically. The Assoc. of University Tech. Managers, *Technology Transfer Stories: 25 Innovations That Changed the World*, 103 (2006), *available at* http://www.autm.net/documents/AUTM_BWR.pdf. Holton eventually licensed his invention to Bristol-Myers Squibb, which introduced the

drug to the marketplace in 1993 and has since been used by more than two million women worldwide. *Id.* at 103–04. Without Holton's invention and the license agreement with Bristol-Myers Squibb, a potent cancer fighting drug would not have been available to millions of women.

Another invention that has saved lives is Exosurf, a synthetic surfactant for use in the lungs that has dramatically cut the death rate of premature infants suffering from respiratory distress syndrome (RDS). *Id.* at 51–54. In 1986, the inventor, John Clements, a university professor and researcher, licensed Exosurf to Burroughs-Wellcome (now GlaxoSmithKline), which brought the drug to market. Since then, use of the drug has dramatically cut infant mortality from RDS. *Id.* Without licensing, this product would have taken much longer to reach the market, and more premature newborns would have died.

B. Public Policy Encourages Upholding the Integrity of Licenses Even if Some Invalid Patents Remain Unchallenged

Allowing a licensee in good standing to challenge the validity of a patent while maintaining the benefits of the license (such as a locked-in, low royalty rate) will disrupt licensing activities and harm the economy. Doing so will make licensing more costly and make patent owners hesitant to license their inventions. If patent owners cannot count on settling disputes through licenses, and if inventors cannot count on their licensees to abide by the patents, then investors and businesses will have less incentive to support research and development and promote the introduction of new technologies. Indeed, common sense dictates that a patent owner will be wary of handing out a license knowing that the recipient will eventually bite the proverbial hand. Such loss of faith in the value of licenses could ultimately

reduce the commercialization of innovative products like the ones recounted above.

Predictability in the patent system is crucial to promoting the costs and risks associated with innovation. In turn, innovation is at the heart of American competitiveness in the global economy. David Silverstein, *Patents, Science and Innovation: Historical Linkages and Implications for Global Technological Competitiveness*, 17 Rutgers Computer & Tech. L.J. 261, 318–19 (1991); *see also Hilton Davis Chem. Co. v. Warner-Jenkinson Co. Inc.*, 62 F.3d 1512, 1529 (Fed. Cir. 1995) ("Technologic innovation has driven the American economy, over the past century, to the exclusion of virtually all other growth factors") (Newman, J, dissenting), *rev'd*, 520 U.S. 17 (1997); Reed Albergotti, *The Most Inventive Towns in America*, Wall St. J., July 22, 2006, at P6 ("One upside of these innovations is that new patents often lead to the creation of new companies, which in turn means more jobs")

Allowing licensees in good standing to maintain declaratory judgment actions while retaining the benefits of their licenses, however, will disrupt the predictability of license agreements and "effectively defeat those contractual covenants and discourage patentees from granting licenses." *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1382 (Fed. Cir. 2004). In other words, the public will lose faith in licenses.

In this case, MedImmune admits that it accepted a license in 1997 to avoid litigation, to settle a dispute. But public policy encourages preserving the integrity of licenses and promoting settlement of actual or threatened litigation, even if some invalid patents remain unchallenged. *See, e.g., Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1368 (Fed. Cir. 2001) ("[W]hile the federal patent laws favor full and free competition in the use of ideas in the public domain over the technical requirements of contract doctrine, settlement of

litigation is more strongly favored by the law"); *accord, In re Tamoxifen Citrate Antitrust Litigation*, 429 F.3d 370, 386-87 (2d Cir. 2005) (citing *Flex-Foot* and observing that rules discouraging settlements of patent litigation "would heighten the uncertainty surrounding patents and might delay innovation"); *see also Schering-Plough Corp. v. Federal Trade Comm'n*, 402 F.3d 1056, 1072 (11th Cir. 2005) ("The general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits"); *Hemstreet v. Spiegel, Inc.*, 851 F.2d 348, 351 (Fed. Cir. 1988) (holding that *Lear v. Adkins*, 395 U.S. 653 (1969), did not preclude the enforcement of a settlement even if the licensed patents may be held invalid or unenforceable); *Wells Cargo, Inc. v. Wells Cargo, Inc.* 606 F.2d 961, 965 (C.C.P.A. 1979) ("If there be a policy favoring challenges to trademark validity, it too has been viewed as outweighed by the policy favoring settlements").

This Court itself recognizes that the exchange of rights and royalties to settle patent litigation "may promote rather than restrain competition." *Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931).

The notion that only invalid patents are likely to be challenged is dubious. Licensees have a strong incentive to challenge patents — no matter whether the case for invalidity is strong or weak — so that they can avoid paying additional royalties. Allowing licensees in good standing to sue will thus skew the balance between licensor and licensee. *See Gen-Probe*, 359 F.3d at 1382 ("[T]he licensor would bear all the risk, while the licensee would benefit from the license's effective cap on damages or royalties in the event its challenge to the patent's scope or validity fails"). Of course, litigation will increase as well.

Even if only invalid patents are challenged, there is no guarantee that the public will reap the benefits. As Circuit

Judge Newman of the Federal Circuit noted, validity challenges do not always benefit the public:

> The Court in *Lear* apparently believed that "full and free competition" ensues when a patent is eliminated from the rolls. The experience of the marketplace is otherwise. The usual incentive to the patent licensee in taking the license is, and always has been, the opportunity for profit. If the destruction of a licensed patent would not enhance profits but instead facilitate the entry of competitors, this would surely be weighed by a licensee before embarking on a *Lear*-authorized challenge to the licensed patent. It is common experience — and common sense — that challenges to patent validity by either licensees or assignors, albeit serving the private interest of the challenger, carry scant public benefit. The nobler expectations of *Lear* have few testimonials.

Diamond Scientific Co. v. Ambico, Inc., 848 F.2d 1220, 1228 (Fed. Cir. 1988) (Newman, J., concurring) (citation omitted).

Rather than pass the benefit of reduced costs on to the public, the unfortunate truth is that licensees like MedImmune will keep for themselves the money they would have paid in royalties and thus enjoy higher profits. Armed with the ability to challenge the validity of patents while protected by license agreements, licensees will have a strong incentive to risk litigation to challenge even valid patents.

Altering the rights of patentees and licensees as MedImmune suggests is not an experiment to undertake lightly. Licensing is too important to the American economy and well-being of the American people to change the expectations of patentees

and licensees simply because one licensee, MedImmune, wants to keep more of its profits for itself. If any such changes in expectations are to occur, they should be the result of open and careful deliberation in Congress, based on the input of many intellectual property creators and users.

CONCLUSION

The Boston Patent Law Association urges this Court to affirm the ruling of the Federal Circuit that a licensee in good standing — who, by definition, has not apprehension of suit — may not create declaratory judgment jurisdiction under Article III merely because it desires to challenge the validity of the licensed patent.

Respectfully Submitted

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